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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,759	07/26/2007	Ardythe L. Morrow	18599-002US1 CHRF 03-1201	6591

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
11/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,759	MORROW ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-39 and 58-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-39 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/08; 7/26/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 33-39, drawn to the prevention/treatment of infection, in the reply filed on July 24, 2009 is acknowledged. All previously pending claims, drawn to nonelected inventions, have been canceled. Claims 58-63 are newly added and fall within the scope of the elected invention. Claims 33-39 and 58-63 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods, each comprising a step of "identifying the two most prevalent agents capable of causing enteric disease in the geographic location of the patient." However, there is no definition of "geographic location." Therefore, one of ordinary skill would not be apprised of what constitutes infringing.

Even if "geographic location" were defined, neither the claims nor the specification set forth any particular method of identifying said agents. A cursory review of the art suggests that there are many methods for surveying pathogens in an area. See for example, Jiang et al (J.

Infect. Dis., 2002) and Pradel et al (J. Clin. Microbiol., 2000). The former tests self-selected hotel guests in three areas, while the latter randomly tests children, cows and food in a region of France. It is not clear that every possible method of surveying pathogens would come up with the same result. The existence of a variety of testing methods that can result in different findings also makes the method indefinite.

Furthermore, it is not clear that this identification step of the method actually requires a tangible action. That is, if the claim is broad enough to embrace any method, one of those might be hearing a news report identifying said pathogens. Again, it is not clear how one would make the determination as to infringement in this case.

For the reasons set forth above, these claims are deemed vague and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-39, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Prieto et al (US 2002/0019991).

Prieto discloses the administration of a composition comprising at least one glycan comprising a fucose in an α1,2 linkage for the prevention or treatment of enteric infections, *V. cholerae* or *E. coli*. See particularly paragraphs [0028]-[0034]. The glycan entities include glycoproteins and glycolipids.

The reference is silent regarding the identification of prevalent pathogens, but as discussed above, it is not clear that the identification step requires any actual tangible action. However, the fact that the reference particularly teaches two particular pathogens suggests the inherent accomplishment of this step.

Claims 33-35, 37, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanmaele et al (US 6,291,435).

Vanmaele teaches the administration of multivalent fucosylated oligosaccharides for the prevention or amelioration of symptoms of enteropathic *E. coli* infection. See, for example, Table 1; col 5, lines 25-54; Table 2; col 11, lines 16-50 and Example 1.

Claims 33-39, 58, 59 and 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Yolken et al (J. Clin. Invest., 1992) with Wilson et al (J. Proteome Res., 2007) to demonstrate inherency.

Yolken teaches the administration of human milk mucin, as well as two glycoprotein components of the mucin complex, to reduce the incidence of infection from rotovirus. See abstract. By administering these agents, the incidence of other infections is also inherently reduced. The reference does not characterize the carbohydrate components of these agents. However, Wilson discloses the structural prediction of a variety of oligosaccharides released from human milk MFGM and the HWM fraction. See Table 2. The reference specifically confirms the presence of Lewis a and Lewis b. See Figure 6 and paragraph 4 at page 3692.

It is known that the agents administered by Yolken are highly glycosylated and known to comprise at least some of the recited glycan entities. However, the Office does not have the facilities for preparing the claimed materials and fully characterizing the carbohydrate components of these agents, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-35, 37 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanmaele et al (US 6,291,435) in view of Stahl et al (US 5,470,843) and Prestwich et al (J. Controlled Release, 1998).

Vanmaele teaches as set forth above. The reference does not teach the administration of a glycosaminoglycan. The reference exemplifies BSA as the support for the multivalent oligosaccharide product. The reference suggests the use of other polymers, such as polysaccharides as supports. See col 7, lines 42-67.

Stahl teaches that various glycosaminoglycans, including hyaluronic acid, have utility as a support for multivalent oligosaccharide products to be administered for the treatment of bacterial and viral disorders. See col 4, lines 6-9 and 33-35; col 7, lines 14-24; and col 8-11.

Prestwich teaches that hyaluronic acid is an immunoneutral polysaccharide that is amenable to multivalent functionalization and highly suitable as a drug delivery vehicle. See entire reference.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polyvalent BSA structure by substituting another suitable polymer for BSA as the support for the polyvalent structure with a reasonable expectation of success because it is suggested by the art. It would be within the scope of the artisan to select one such as hyaluronic acid because it is known to be useful in preparing similar products having similar utility to those disclosed in Vanmaele.

Claims 33-39, 58, 59, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prieto et al (US 2002/0019991).

Prieto teaches as set forth above. The reference does not specifically teach the identification of prevalent pathogens.

The reference is particularly drawn to the prevention and treatment of *V. cholerae* and *E. coli* and does not specifically address prevention and treatment of *C. jejuni*. However, the reference specifically discloses avid binding (indication of utility in prevention/treatment of pathogen) with some of the described oligosaccharides, particularly H-2 (Fucα1-2Galβ1-4GlcNAc). See example I.

The reference does not particularly disclose a composition or conjugate having more than one oligosaccharide. However, the reference specifically suggests compositions and glycoconjugates (including glycoproteins) having "*at least one* fucose residue in an α1-2 linkage." (emphasis added) See for example, paragraph [0031].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to identify the most prevalent pathogens in the geographic area of a patient to determine to which agent the patient is susceptible in order to determine what therapeutic protocol would be most beneficial to that patient. It would be further obvious to use a composition disclosed comprising H-2 for the prevention/treatment of *C. jejuni* with a reasonable expectation of success because the reference discloses strong binding of *C. jejuni* with this oligosaccharide. Finally, it would be further obvious to prepare compositions or glycoconjugates, including glycoproteins, having more than one of the recited oligosaccharides with a reasonable expectation of success because it is suggested by the art.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:30 to 4:00 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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/Leigh C. Maier/
Primary Examiner
Art Unit 1623